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KNOBBE MARTENS OLSON & BEAR LLP			EXAMINER	
2040 MAIN STREET			CHUNDURU, SURYAPRABHA	
FOURTEENTH FLOOR				
IRVINE, CA 92614				
			ART UNIT	PAPER NUMBER
			1637	
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			10/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/543,017

Applicant(s)

MILLAR ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-64 is/are pending in the application.
- 4a) Of the above claim(s) 60-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I (claims 33-59) in the reply filed on September 14, 2007 and the Preliminary Amendment filed on July 22, 2005 are considered and acknowledged.

Applicants' correction of the status of pending claims is acknowledged. Applicants neither indicated whether the election is with traverse or without traverse nor provided any arguments for traversal. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status

2. Claims 1-32 are canceled by the Preliminary Amendment filed July 22, 2005. New claims 33-64 (which read on cancelled claims) are added by the Preliminary Amendment. Claims 33-59 are considered for examination and Claims 60-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. This is made FINAL.

Priority

3. This application filed on July 24, 2006 is a 371 of PCT/ AU04/00083 filed on November 23, 2004, which claims benefit of foreign application AU 2003900368 filed on 1/24/03.

Information Disclosure Statement

4. The Information Disclosure Statement filed on April 25, 2006 has been considered and acknowledged.

Sequence Rules and Objection to the Specification

5. The specification is objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least page 71, line 30) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Examiner also notes that the application contains no sequence listing either in the form of a paper copy or in a computer readable form. Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 33-44, 46, 55-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eads et al. (Nucleic Acids Res., Vol.28, No. 8, pp. e32 i-viii, 2000) in view of Christensen et al. (Nucleic Acids Res., Vol. 30, No. 22, pp. 4918-4925, 2002).

Eads et al. teach a method of claim 33, for detecting the presence of a target nucleic acid in a sample comprising

(a) treating a sample containing nucleic acid with an agent that modifies unmethylated cytosine (see page e32 ii, col. 1, paragraph 3 under Materials and Methods section);

(b) providing to the treated sample a detector ligand (probe) capable of binding to a target region of nucleic acid and allowing sufficient time for the detector to bind to the target nucleic acid (see page e32 ii, col. 2, line 1-8) and

(c) detecting the binding of the detector ligand to the nucleic acid molecule in the sample as an indication of the presence of the target (see page e32 ii, col. 2, line 4-8).

With regard to claim 34, 36, Eads et al. teach that the nucleic acid is obtained from genomic DNA (see page e32 ii, col. 1, paragraphs 1-3 under Materials and Methods section).

With regard to claims 37-38, Eads et al. teach that the agent is sodium bisulfite (see page e32 ii, col. 1, paragraph 3 under Materials and Methods section).

With regard to claims 41-42, Eads et al. teach that the detector ligand is directed to a CpG containing region which includes a promoter region (see page e32 iii, col. 1, paragraph 2 under Results section).

With regard to claims 43-44, Eads et al. teach that prior to treating the sample, the nucleic acid undergoes an enrichment step that comprises chemical treatment to isolate DNA (see page e32 ii, col. 1, paragraph 2 under Materials and Methods section).

With regard to claims 55-56, Eads et al. teach that the detector ligand comprises a fluorescent label (see page e32 ii, col. 2, line 1-8).

With regard to claims 57-58, Eads et al. teach that the nucleic acid bound to the detector ligand is further processed by polymerase chain reaction using primers directed to the regions of nucleic acid (see page e32 ii, col. 2, line 1-24).

However Eads et al. did not teach use of an intercalating detector nucleic acid to detect the target nucleic acid.

Christensen et al. teach a method for detecting and discriminating DNA over RNA, wherein the method comprises the use of INA as a detector ligand that can discriminate between DNA/DNA and RNA/DNA hybrids (see page 4918, abstract, page 4919, col. 1, paragraphs 1-2 under Materials and methods, page 4920, col. 2, paragraph 4, page 4921, col. 2, paragraph 2, page 4922, col. 2, paragraph 1-2). Christensen et al. also teach that said INA is O-pyrenylmethylglycerol and the target includes chimeric nucleic acid (see page 4918, abstract, page 4919, col. 2, paragraph 3).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine or modify the method the method of detecting the presence of a target nucleic acid in a sample as taught by Eads et al. with a step of using intercalating detector ligands as taught by Christensen et al. to achieve expected advantage of developing a sensitive method that can discriminate between DNA/DNA and DNA /RNA hybrids. The ordinary artisan would have motivated to combine the method of Eads et al. with Christensen et al. because the ordinary artisan would have had a reasonable expectation of success that the combination would result in discriminating between DNA/DNA and DNA/RNA hybrids because

Christensen et al. explicitly taught that the binding of INA with the target nucleic acid increases the stability of the DNA the differential stabilities of the hybrids can be used to discriminate between DNA and RNA (see page 4922, col. 2, paragraph 3, page 4923, col. 1, line 1-9, col. 2, line 1-8) and such modification is considered as obvious over cited prior art.

B. Claims 45, 47-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eads et al. (Nucleic Acids Res., Vol.28, No. 8, pp. e32 i-viii, 2000) in view of Christensen et al. (Nucleic Acids Res., Vol. 30, No. 22, pp. 4918-4925, 2002) as applied to claims 33-46, 55-59 above, and further in view of Shah et al. (USPN. 5,629,156).

Eads et al. in view of Christensen et al. teach a method for detecting the presence of a target nucleic acid as discussed above in section 6A.

However neither Eads et al. nor Christensen et al. teach the use of a capture ligand and use of a solid support to immobilize target nucleic acid.

Shah et al. teach a method of detecting a target nucleic acid wherein Shah et al. disclose that the method comprises hybridizing a target nucleic acid (DNA or RNA) to a capture probe (capture ligand or biotinylated capture probe) and a detector probe (signal probe), and detecting the bound hybrid (see column 7, lines 17-29, column 3, lines 60-67, column 4, lines 1-51, and column 6, lines 30-57). Shah et al. also teaches immobilization of capture probe on to a solid support (see column 4, lines 29-32); Further Shah et al. teach use of dA-tailed capture probes which bind to both target and dT derivitized supports such that the binding is stronger to the targets than the supports (see column 8, lines 44-54); capture probes biotinylated at both ends (column 9, lines 58-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of detecting a target nucleic acid as taught by Eads et al. in view of Christensen et al. with the step of adding capture ligand and a solid support for immobilization of capture probes as taught by Shah et al. to achieve expected benefit of developing an enhanced and improved method for detecting a nucleic acid. One of the ordinary person skilled in the art would have a reasonable expectation of success that the combination would result in reducing the background signal noise because Shah et al. explicitly taught that 'the new assay format eliminates noise due to nonspecific binding of the detector probe to the capture probe and can produce a sandwich hybridization assay entirely free of background noise (see col. 3, line 49-64). In order to reduce signal to noise ratio in hybridization assays involving DNA-RNA interaction, an ordinary practitioner would have been motivated to modify the method of detecting a target nucleic acid as taught by Eads et al. in view of Christensen et al. by incorporating the capture probes and immobilizing the capture probes as taught by Shah et al. to develop a method that would improve sensitivity and specificity of detecting a target nucleic acid which would result in reduced background signal noise and enhanced sensitivity and specificity of the detection method and such a modification of the method is considered to be obvious over the cited prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Suryaprabha Chunduru
SURYAPRABHA CHUNDURU 10/15/07
PRIMARY EXAMINER